

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF FLORIDA  
ORLANDO DIVISION**

**PEGGY ROGERS,**

**Plaintiff,**

**v.**

**Case No: 6:20-cv-1551-PGB-EJK**

**COLOPLAST CORP.,  
COLOPLAST A/S and  
COLOPLAST  
MANUFACTURING US, LLC,**

**Defendants.**

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**ORDER**

This cause comes before the Court on Defendant Coloplast A/S's Motion to Dismiss for Lack of Personal Jurisdiction (Doc. 73 (the "**Motion**")), Plaintiff's Response in Opposition (Doc. 77 (the "**Response**")), and Defendant's Reply thereto (Doc. 84 (the "**Reply**")). Upon consideration, the Motion is due to be granted.

**I. BACKGROUND**

This products liability action concerns Restorelle mesh and the Aris sling (collectively, the "**Products**"), which are devices manufactured to treat pelvic organ prolapse ("**POP**") and stress urinary incontinence ("**SUI**"). (Doc. 67, ¶¶ 59–60, 64).

Plaintiff is a resident of the State of Florida. (*Id.* ¶ 1). On April 13, 2011, Plaintiff underwent surgery to treat POP and SUI at Winnie Palmer Hospital in

Orlando, Florida (*Id.* ¶¶ 59–61). During surgery, Plaintiff was implanted with the Products without intraoperative complications. (*Id.* ¶¶ 62, 64). Plaintiff’s doctor read and relied on the Products’ Instructions for Use (the “**IFUs**”) before performing the surgery. (*Id.* ¶¶ 41–42).

Plaintiff claims that the Products were defective, which caused her to develop cystocele, rectocele, enterocele, pelvic pains, and dyspareunia. (*Id.* ¶ 65). These injuries required surgery to remove the Products. (*Id.*).

Plaintiff filed her complaint on August 26, 2020. (*Id.*). Therein, Plaintiff sued three defendants: (1) Coloplast A/S; (2) Coloplast Corp.; and (3) Coloplast Manufacturing US, LLC. (*Id.* ¶¶ 2–4). Defendant Coloplast A/S (“**Defendant**”) moved the Court to dismiss it for lack of personal jurisdiction. (Doc. 41). In ruling, the Court found: the Florida Long-Arm Statute was satisfied; the first prong of the personal jurisdiction Due Process inquiry was satisfied; but the second prong of the personal jurisdiction Due Process inquiry was not satisfied by the facts as alleged. (Doc. 49, pp. 14–16). Nevertheless, the Court afforded the parties an opportunity to conduct limited jurisdictional discovery so that the Plaintiff could file an amended complaint which might cure the original complaint’s jurisdictional defects. (*Id.* at p. 16). After this jurisdictional discovery, Plaintiff filed the Amended Complaint. (Doc. 67). Defendant again moves to dismiss the claims against it for lack of personal jurisdiction, arguing that Plaintiff did not sufficiently fortify its pleadings. (Doc. 73).

## II. STANDARD OF REVIEW

District courts in the Eleventh Circuit apply a two-prong test to determine whether personal jurisdiction exists over a defendant. *Mutual Serv. Ins. v. Frit Indus., Inc.*, 358 F.3d 1312, 1319 (11th Cir. 2004); *Cable/Home Commc’n Corp. v. Network Prods., Inc.*, 902 F.2d 829, 855 (11th Cir. 1990). Ordinarily, the court must first determine whether the plaintiff has alleged sufficient facts to subject the defendant to the forum state’s long-arm statute. *See Future Tech. Today*, 218 F.3d at 1249. If jurisdiction is established under the forum state’s long-arm statute, the court must then decide whether the exercise of jurisdiction comports with the Due Process Clause of the Fourteenth Amendment to the United States Constitution. *Id.*

When a defendant moves to dismiss for lack of personal jurisdiction under Rule 12(b)(2), the plaintiff must allege facts sufficient to establish that the court has personal jurisdiction over the defendant and to rebut a defendant’s assertion that jurisdiction over him is improper. *Smith v. Trans-Siberian Orchestra*, 689 F. Supp. 2d 1310, 1313 (M.D. Fla. 2010) (citing *Future Tech. Today, Inc. v. OSF Healthcare Sys.*, 218 F.3d 1247, 1249 (11th Cir. 2000)). Ordinarily, in the face of conflicting evidence at the motion to dismiss stage, “reasonable inferences are drawn in the plaintiff’s favor.” *See 3Lions Publ’g, Inc. v. Interactive Media Corp.*, 389 F. Supp. 3d 1031, 1036 (M.D. Fla. 2019). However, the plaintiff faces a higher burden following jurisdictional discovery. *See Gen. Elec. Credit Corp. v. Scott’s Furniture Warehouse Showroom, Inc.*, 699 F. Supp. 907, 910 (N.D. Ga. 1988).

Specifically, the plaintiff must allege facts that establish personal jurisdiction by a preponderance of the evidence, “affidavits based on personal knowledge are to be credited over contradictory allegations based merely on information and belief, and facts adduced in opposition to jurisdictional allegations are considered more reliable than mere contentions offered in support of jurisdiction.” *Id.*; see also *In re Farmland Indus., Inc.*, No. 3:05-CV-587-J-32MCR, 2007 WL 1018367, at \*2 (M.D. Fla. Mar. 20, 2007) (holding that “the plaintiff[] [bears] the burden of proving by a preponderance of the evidence the facts necessary to establish personal jurisdiction over the defendant” following jurisdictional discovery).<sup>1</sup>

### **III. DISCUSSION**

The crux of Defendant’s argument is that Plaintiff’s Amended Complaint ignores the corporate distinctions between Defendant and its subsidiaries and contravenes the evidence produced during jurisdictional discovery with conclusory or unsupported allegations. (Doc. 73, pp. 1–2). The Court agrees. Because the Court ultimately finds that subjecting the Defendant to suit in Florida would not comport with Due Process, the Court need not revisit its previous findings that Florida’s Long-Arm Statute is satisfied. (Doc. 49).<sup>2</sup> To the Due Process analysis, therefore, the Court now turns.

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<sup>1</sup> Plaintiff repeatedly cites to cases that did not involve jurisdictional discovery. (*See, e.g.*, Doc. 77, pp. 8, 12 )(citing *Cableview Commc’ns of Jacksonville, Inc. v. Time Warner Cable Se. LLC*, No. 3:13-CV-306-J-34JRK, 2014 WL 1268584, at \*4 (M.D. Fla. Mar. 27, 2014)). Therefore, Plaintiff’s preferred standard of review is inapplicable.

<sup>2</sup> The Court pauses to note, however, that this finding is on much shakier ground given the relatively higher burden of proof Plaintiff would now face compared to before jurisdictional discovery. See also *Almond v. Coloplast A/S*, 8:20-CV-731-WFJ-AEP, 2021 WL 2042659

## A. The Due Process Inquiry

Personal Jurisdiction must comport with the Due Process Clause of the Fourteenth Amendment. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291 (1980). “The canonical decision in this area remains [*International Shoe*]. There, the Court held that a tribunal’s authority depends on the defendant’s having such contacts with the forum State that the maintenance of the suit is reasonable and does not offend traditional notions of fair play and substantial justice.” *Ford Motor Co. v. Mont. Eighth Jud. Dist. Ct.*, 141 S. Ct. 1017, 1024 (2021) (internal quotation marks and citations omitted). The Eleventh Circuit operationalized the doctrine into a three-part test wherein a court considers:

(1) whether the plaintiff’s claims arise out of or relate to the defendant’s contacts with the forum; [the (“**Relatedness Prong**”)];

(2) whether the nonresident defendant has purposefully availed itself of the forum; [the (“**Purposeful Availment Prong**”)]; and

(3) whether applying personal jurisdiction comports with traditional notions of fair play and substantial justice [the (“**Fair Play Prong**”)].

*Louis Vuitton Malletier, S.A. v. Mosseri*, 736 F.3d 1339, 1355 (11th Cir. 2013) (citations and internal quotations omitted).

“The plaintiff bears the burden of establishing the first two prongs, and if the plaintiff does so, a defendant must make a compelling case that the exercise of

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(M.D. Fla. May 21, 2021) (holding that a similar suit against Defendant could not proceed without violating Florida’s Long-Arm Statute after an opportunity to conduct jurisdictional discovery).

jurisdiction would violate traditional notions of fair play and substantial justice.” *Id.* at 1355 (quoting *Diamond Crystal Brands, Inc. v. Food Movers Int’l, Inc.*, 593 F.3d 1249, 1267 (11th Cir. 2010)).

For the purposes of this Order, the Court will assume, as found previously, that the first Relatedness Prong of the Due Process inquiry is satisfied. (Doc. 49, p. 11). Instead, the Court turns its attention to the second Purposeful Availment prong, which Plaintiff did not satisfy during its first attempt. Plaintiff again misses the mark.

To exercise specific personal jurisdiction over a nonresident defendant, the defendant must have purposefully availed itself of the forum state. *See Hanson v. Denckla*, 357 U.S. 235, 254 (1958). As the Court detailed in its Order on Defendant’s First Motion to Dismiss for Lack of Personal Jurisdiction, the proper purposeful availment test governing foreign manufacturers of goods is whether there is a “regular . . . flow or course of sales in the forum” or if the defendant has entered the goods into the stream of commerce and done “something more.” *J. McIntyre Mach., Ltd. v. Nicastro*, 564 U.S. 873, 889–90 (2011) (Breyer, J. concurring). This “something more” could be: advertising directed at the forum state, a design made to target the forum’s market, communication channels with customers in the forum state, or marketing and distributing the product through a sales agent in the forum state. *See Asahi Metal Indus. Co. v. Superior Ct. of Cal.*, 480 U.S. 102, 112 (1987). Several circuit courts and at least one trial court in the

Eleventh Circuit have held that this test is controlling under the *Marks* rule.<sup>3</sup> Thus, Plaintiff must show a “regular flow” of products into Florida or “something more” directed at Florida for the Court to assert personal jurisdiction over Defendant. *Nicastro*, 564 U.S. at 889–90.<sup>4</sup> Importantly, general targeting of the United States, rather than specific targeting of the forum state in question, cannot confer jurisdiction; “to adopt this view would abandon the heretofore accepted inquiry of whether . . . it is fair, in light of the defendant’s contacts *with that forum* to subject the defendant to suit there.” *Id.* at 891 (emphasis added).

1. *Findings of Fact*

Defendant is incorporated and operates in Denmark. (Doc. 67, ¶ 2). Defendant has no offices in the United States and maintains its business records exclusively in Denmark. (Doc. 41-1, ¶¶ 7, 9). Coloplast Corp. and Coloplast Manufacturing US, LLC, are wholly owned, US-based subsidiaries of Defendant.

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<sup>3</sup> See *Marks v. United States*, 430 U.S. 188, 193 (1977) (“When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds . . . .”)

See, e.g., *Plixer Int’l Inc. v. Scrutinizer GmbH*, 905 F.3d 1, 20 (1st Cir. 2018) (“[Justice Breyer’s] holding was the narrowest and controls here.”); *Williams v. Romarm, SA*, 756 F.3d 777, 784 (D.C. Cir. 2014) (finding Justice’s Breyer’s opinion controlling); *Ainsworth v. Moffett Eng’g, Ltd.*, 716 F.3d 174, 178 (5th Cir. 2013) (same); *AFTG-TG, LLC v. Nuvoton Tech. Corp.*, 689 F.3d 1358, 1363 (Fed. Cir. 2012) (same); *Zanakis v. Scanreco, Inc.*, No. 18-cv-21813, 2019 WL 2211872, at \*8 (S.D. Fla. Feb. 6, 2019) (“[I]n the absence of guidance from the Eleventh Circuit, Justice Breyer’s concurrence in *Nicastro* . . . controls.”).

<sup>4</sup> In *Nicastro*, Justice Breyer found that there was no jurisdiction over a foreign manufacturer because the manufacturer had placed goods into the stream of commerce intending to target the United States as a whole, but not the forum state. 564 U.S. at 889–90.

(Doc. 67, ¶¶ 3–4).<sup>5</sup> In 2006, Defendant acquired Mentor Corporation (“**Mentor**”), which owned and launched the Aris sling. (*Id.* ¶¶ 18–19). In 2010, Defendant also acquired Mpathy Medical Devices, Inc. (“**Mpathy**”), which designed the Restorelle mesh prior to Defendant’s acquisition.<sup>6</sup> (*Id.* ¶ 27). Nevertheless, Defendant itself does not sell, market, or advertise the Products in the United States, let alone Florida. (*Id.* ¶ 24).

Instead, Coloplast Corp. and Defendant’s other domestic subsidiaries are responsible for such activities. (*See id.* ¶¶ 8–26). Since at least 2008, Coloplast Corp. has been responsible for “clinical, medical and operational decisions” related to its Interventional Urology unit. (*Id.* ¶¶ 8, 26).<sup>7</sup> Further, Coloplast Corp. is independently managed. (*Id.* ¶ 11). It maintains separate profits and losses and keeps its own books. (*Id.* ¶ 13). Coloplast Corp. has the right to hire and fire its employees. (*Id.* ¶ 12). Coloplast Corp.’s Interventional Urology employees do not report to Defendant—and Defendant does not have its own employees within the unit. (*Id.* ¶¶ 8, 26). But Defendant “provides oversight of the unit from a budgetary and administrative perspective.” (*Id.* ¶ 25). These attestations are supported by deposition testimony produced during jurisdictional discovery. (*See* Doc. 73-1).

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<sup>5</sup> Both Coloplast Corp. and Coloplast Manu. US, LLC, are Delaware corporations with their principal places of business in Minnesota. (Doc. 67, ¶¶ 3–4).

<sup>6</sup> Neither Mpathy nor Mentor are party to this case.

<sup>7</sup> This unit is responsible for all clinical, regulatory, marketing, research and development, and manufacturing decisions related to the female pelvic health business in the United States. (Doc. 41, p. 3).

Moreover, despite Plaintiff's conclusory allegations to the contrary, Coloplast Corp. "employs the sales representatives who market" the Products "to doctors in Florida." (*Id.* 29:11–13, 37:17–22). Defendant has not "ever employed a sales rep to operate in the United States." (*Id.* 29:14–16). Coloplast Corp. has been wholly "responsible for physician education on the Aris sling . . . [s]ince at least late 2008." (*Id.* at 29:17–30:3). Defendant has not "ever had responsibility for physician education on Restorelle." (*Id.* 38:1–6). Coloplast Corp. has been "responsible for conduct[ing] clinical studies on the Aris sling . . . [s]ince at least late 2008." (*Id.* 30:14–20). And Defendant has not "ever had responsibility for clinical studies on Restorelle." (*Id.* 38:7–13).

Plaintiff points to Mpathy's marketing, physician training, and research activities relating to the Restorelle mesh conducted by Florida Surgeon Dr. Ralph Zipper, either imputing them to Defendant or alleging Defendant was somehow involved in them. (Doc. 77, pp. 7–8, 10–11). But the documentary evidence in support of these allegations is scant, and Plaintiff frequently cites to the Amended Complaint rather than competent proof to fill in evidentiary gaps. (*See id.*). Crucially, the Court cannot locate any proof in the documentary evidence cited by Plaintiff that Defendant itself undertook the alleged activities rather than one of its subsidiaries or their agents. For one, Plaintiff points to Mpathy emails to Dr. Zipper from 2007 and 2008 to support its allegation that Defendant directed marketing or research activities specifically at the state of Florida, but these took place before Defendant acquired Mpathy in 2010. (*Id.* ¶ 27). Despite the allegations

in the pleadings and Plaintiff's vague citations, the Court cannot locate any specific documentary evidence that links Dr. Zipper's work related to the Products in Florida and the Defendant itself.

Plaintiff further alleges that "Defendant had a Mesh Steering Group that oversaw the [Product's] launch strategy and campaign in 2012," which was overseen by Steffen Hovard, who Plaintiff alleges worked for Defendant during this time. (Doc. 77, pp. 11–12; Doc. 77-8; Doc. 77-9; Doc. 77-10; Doc. 77-11). But Plaintiff neglects to include relevant portions of Hovard's deposition, which explain Hovard was employed by Coloplast Corp., not Defendant, during this time. (Doc. 84, pp. 9–10; Doc. 84-4).

At the same time, Defendant holds the patents to the Products. (Doc. 67 ¶ 29). Defendant is identified as an "Owner/SUBMITTER" on a 510(k) Premarket Notification submitted to the U.S. Food and Drug Administration ("**FDA**") for Restorelle mesh. (Doc. 43-1).<sup>8</sup> The Products' IFUs further identified Defendant as the "Manufacturer" and contain its name and trademark. (Docs. 43-2; 43-3). Despite this listing in the IFUs, testimony produced in jurisdictional discovery demonstrates that either Coloplast Corp. manufactured the Products, that Coloplast Corp. drafted the Products' IFUs, and that any manufacturing

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<sup>8</sup> "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent, to a legally marketed device (section 513(i)(1)(A) FD&C Act). Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims." U.S. FOOD AND DRUG ADMIN., PREMARKET NOTIFICATION 510(k), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> (last updated 3/13/2020).

attribution to Defendant is error attributable to Coloplast Corp., not Defendant. (Doc. 73-1, 21:16–19, 23:5–10, 33:17–23, 34:12–21). The *Almond* court in the Middle District of Florida recently found as much after jurisdictional discovery in a similar case to the one here. *Almond v. Coloplast A/S*, 8:20-CV-731, 2021 WL 2042659, at \*4–5 (M.D. Fla. May 21, 2021).

## 2. *Conclusions of Law*

Under the regular flow and stream of commerce test, Plaintiff still fails to satisfy the purposeful availment prong of the Due Process analysis. First, as to a “regular flow” of goods, Plaintiff does not provide a non-conclusory indication of how many of Defendant’s products made their way to Florida, nor a total value for such sales. Without such allegations, the Court cannot conclude that Defendant’s products regularly flowed into Florida. Simply manufacturing a single product that ends up in the forum state is not enough. *See id.* at 888 (“None of our precedents finds that a single isolated sale . . . is sufficient.”) (Breyer, J. concurring). Moreover, Plaintiff has not established that Defendant is the Products’ manufacturer during the relevant time period with a preponderance of the evidence after jurisdictional discovery. Indeed, the weight of the evidence cuts against a finding that Defendant releases or initiates *any* flow of the Products into Florida, let alone a regular flow of such goods. After all, Coloplast Corp.’s Vice President of Global Operations testified that Coloplast Corp., not Defendant, was “responsible for the manufacturing of [the Products] from 2010 to . . . May 2020.” (Doc. 73-1, 20:1–12, 21:16–19, 33:17–23).

Similarly, Plaintiff still provides insufficient evidence that Defendant did “something more.” Even if the Court assumed that Defendant is indeed the manufacturer of the Products because of the IFUs, Plaintiff could only demonstrate, at a maximum, that Defendant put the Products into the stream of commerce. Seeing the writing on the wall, Plaintiff puts forward conclusory allegations or allegations which are not supported by the record produced during jurisdictional discovery. For example, Plaintiff alleges that Defendant directed advertising at Florida, designed the Products to target the Florida market, communicated with customers in Florida, or marketed the product through a sales agent in Florida—all assertions supported by pointing to Dr. Zipper’s 2007 and 2008 emails between himself and Mpathy representatives or an agreement between Dr. Zipper and Coloplast Corp. to conduct research potentially related to the Products. (Doc. 67; Doc. 77, pp. 8–12; Docs. 77-2, 77-3, 77-4, 77-5, 77-6, 77-7). But Plaintiff’s cited evidence can only demonstrate that Defendant’s related entities—Mpathy or Coloplast Corp.—did “something more” directed at the forum, not Defendant itself. The allegations are not enough when Defendant has competent testimony which directly undercuts Plaintiff’s unsupported assertions. (Doc. 41-1; Doc. 73-1, 20:1–12, 21:13–19, 23:5–10, 28:2–16, 33:14–23, 34:12–21, 36:23–25).

The rest of Plaintiff’s allegations fare no better. Notably, Plaintiff asserts that “[Defendant] had a Mesh Steering Group that oversaw the [Product’s] launch strategy and campaign in 2012,” which was overseen by Steffen Hovard who

Plaintiff alleges worked for Defendant during this time. (Doc. 77, pp. 11–12; Doc. 77-8; Doc. 77-9; Doc. 77-10; Doc. 77-11). But Defendant rightly points out that this assertion is undercut by the fact that Plaintiff omitted relevant portions of Hovard’s deposition which demonstrate he was employed by Coloplast Corp. at this time, not Defendant. (Doc. 84, pp. 9–10; Doc. 84-4). Even if the Court were to assume Hovard also worked for Defendant as part of this Steering Group, Plaintiff has not sufficiently shown that the Steering Group’s work was directed specifically at the forum state of Florida, rather than the United States in general.

In other words, at each turn Plaintiff fails to support her allegations with either specific facts or facts supported by “affidavits or other competent proof,” instead merely reiterating factual allegations contained in her complaint or citing to evidence which cannot reasonably be said to support her claims. *Polskie Linie Oceaniczne v. Seasafe Transport A/S*, 795 F.2d 968, 972 (11th Cir. 1986) (noting that plaintiffs must respond to fact-based jurisdictional challenges through “affidavits or other competent proof, and [cannot] merely reiterate the factual allegations in the complaint.”). This lack of competent proof is particularly problematic because the Court provided Plaintiff the opportunity to conduct jurisdictional discovery. (Doc. 49). Plaintiff cannot now rescue her claims against Defendant with unsubstantiated accusations and tenuously supported assumptions in the face of Defendant’s evidence to the contrary. (Docs. 41-1, 73-1, 73-2, 73-3, 73-4, 73-5, 84-4).

In summary, Plaintiff still has not met their burden to show that Defendant

purposefully availed itself of the laws of the forum state of Florida. On this record, it is improper for the Court to exercise personal jurisdiction over Defendant.<sup>9</sup>

#### **IV. CONCLUSION**

1. Defendant Coloplast A/S's Motion to Dismiss (Doc. 73) is **GRANTED**;
2. Plaintiff's Amended Complaint (Doc. 67) is **DISMISSED WITHOUT PREJUDICE**;
3. Plaintiff may file a Second Amended Complaint on or before February 11, 2022, against the two remaining defendants, provided it can do so consistent with the directives of this Order.

**DONE AND ORDERED** in Orlando, Florida on January 27, 2022.

  
PAUL G. BYRON  
UNITED STATES DISTRICT JUDGE

Copies furnished to:

Counsel of Record  
Unrepresented Parties

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<sup>9</sup> Because Plaintiff again fails to satisfy the second Purposeful Availment prong of the Due Process analysis, there is no need to address the third Fair Play prong.